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A Phase III randomised trial of perioperative chemotherapy versus surveillance in upper tract urothelial cancer

Submission date 31/01/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/01/2012	**Overall study status** Completed	
Last Edited 03/04/2020	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-after-surgery-cancer-kidney-ureter-pout

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-002577-33

IRAS number
82914

ClinicalTrials.gov number
NCT01993979

Secondary identifying numbers
11494, IRAS 82914

Study information

Scientific Title
A Phase III randomised trial of PeriOperative chemotherapy versus sUrveillance in upper Tract urothelial cancer

Acronym
POUT

Study objectives
POUT is a phase III multicentre randomised controlled trial. The objective is to determine the efficacy, safety and effects on patients quality of life of adjuvant chemotherapy in patients who have undergone radical nephro-ureterectomy for upper urinary tract transitional cell carcinoma (TCC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/NE/0332

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Bladder Cancer, Renal Cancer; Disease: Urothelium

Interventions

Chemotherapy, Gemcitabine 1000mg/m2 day 1 and day 8 as 30 minute intravenous infusion in 500ml sodium chloride; and

Cisplatin 70mg/m2 day 1 as a 4 hour intravenous infusion or (for participants with a creatinine clearance of 25-49ml only) Carboplatin AUC 4.5 or AUC 5 (according to local practice)

Carboplatin will be given to patients who are fit for chemotherapy and fulfil all trial entry criteria but have GFR 30-49 ml/min.

Surveillance, Patients allocated to surveillance will be seen at 4, 7, 10 and 13 weeks post randomisation - equivalent to the end of cycle in patients receiving chemotherapy. Patients on surveillance will then be followed up for signs of recurrence at the same intervals as those who received chemotherapy.; Follow Up Length: 60 month(s)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, cisplatin, carboplatin

Primary outcome measure
Disease free survival; Timepoint(s): The main time point of interest is three years after randomisation.

Secondary outcome measures
1. Acute toxicity; Timepoint(s): Whilst patients are on treatment and up to 3 months post-randomisation
2. Contralateral second primary utTCC; Timepoint(s): The primary timepoint of interest is 3 years
3. Invasive recurrence/second primary in the bladder; Timepoint(s): The primary timepoint of interest is 3 years after randomisation
4. Late toxicity; Timepoint(s): 6 months, 2 years
5. Metastasis free survival; Timepoint(s): The primary timepoint of interest is 3 years.
6. Overall survival; Timepoint(s): The primary timepoint of interest is 3 years after randomisation
7. Quality of life (QoL) as measured by the EORTC QLQ-C30 and EQ5D modules.; Timepoint(s): We are collecting information on QoL up to 2 years post randomisation
8. Treatment compliance (in the chemotherapy arm); Timepoint(s): Once chemotherapy has been completed; Trial feasibility; Timepoint(s): Defined by recruitment over the first two years

Overall study start date
01/03/2012

Completion date
01/03/2017

Eligibility

Key inclusion criteria

1. Written informed consent
2. >or =18 years of age
3. Post radical nephro-ureterectomy for upper tract tumour with predominant TCC component - squamoid differentiation or mixed TCC/ small cell carcinoma (SCC) is permitted
4. Histologically confirmed TCC staged pT2-pT4 pN0-3 M0 or pTany N1-3 M0 (providing all grossly abnormal nodes are resected). Patients with microscopically positive margins on pathology may be entered (providing all grossly abnormal disease was resected)
5. Satisfactory haematological profile (ANC> 1.5 x 109/L, platelet count 100 x 10/L) and liver function tests (bilirubin < 1.5 x ULN, AST and Alkaline phosphatase < 2.5 x ULN), Glomerular filtration rate = 30 mls/min
6. Fit and willing to receive adjuvant chemotherapy with first cycle to be commenced within 90 days of radical nephro-ureterectomy if allocated
7. WHO performance status 0-1.
8. Available for long-term follow-up; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 345; UK Sample Size: 256

Total final enrolment
261

Key exclusion criteria
1. Evidence of distant metastases
2. Pure adenocarcinoma, squamous cell carcinoma or small cell or other variant histology
3. Un-resected macroscopic nodal disease
4. Concurrent muscle invasive bladder cancer (patients with concurrent Non-muscle invasive bladder cancer (NMIBC) will be eligible)
5. Glomerular filtration rate (GFR) <30 ml/minute. Gemcitabine-carboplatin can only be given for patients with suboptimal renal function for cisplatin ie for GFR 30-49ml/min. Patients with poor performance status or co-morbidities that would make them unfit for chemotherapy are ineligible for the trial
6. Significant co-morbid conditions that would interfere with administration of protocol treatment
7. Pregnancy; lactating women or women of childbearing potential unwilling or unable to use adequate non-hormonal contraception (male patients should also use contraception if sexually active)
8. Previous malignancy in the last 5 years except for previous NMIBC, adequately controlled non

melanoma skin tumours, carcinoma in situ (CIS) of cervix or Lobular carcinoma in situ (LCIS) of breast or localised prostate cancer in patients who have a life expectancy of over 5 years upon trial entry

Date of first enrolment
01/03/2012

Date of final enrolment
10/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
15 Cotswold Road
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SM2 5NG

Sponsor information

Organisation
Institute for Cancer Research (UK)

Sponsor details
Section of Clinical Trials, 15 Cotswold Road
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Sponsor type
Research organisation

Website
http://www.icr.ac.uk/

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Government

Funder Name
Clinical Trials Awards and Advisory Committee (CTAAC) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Abstract results	conference abstract	20/02/2018		No	No
Results article	results	18/04/2020	10/03/2020	Yes	No